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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,773	07/20/2004	Karl Kolter	53272	8423

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NOVAK DRUCE DELUCA & QUIGG, LLP
1300 EYE STREET NW
SUITE 400 EAST
WASHINGTON, DC 20005

EXAMINER

RAZA, SAIRA B

ART UNIT	PAPER NUMBER
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1711

DATE MAILED: 03/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/501,773

Applicant(s)

KOLTER ET AL.

Examiner

Saira Raza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 3,4,6,8,9,12-19 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 1,2,5,7,10,11,20,27,28 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) 1-28 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-20 and 27-28, drawn to a coating composition, classified in class 525.

Group II, claim(s) 21-26, drawn to a process for producing coated substrates, classified in class 427.

2. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Claim 1, at least, is anticipated or obvious over WO/00/18375 (Page: Lines: 1:5-12, 4:3-11, 19:10-34, Example 7). Consequently, the special technical feature which links claims 1-28, a composition comprised of component A, B, and C, does not provide a contribution over the prior art, so unity of invention is lacking and no single general inventive concept exists. Therefore, restriction is appropriate.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species groups are as follows:

1. Component B
2. Component C

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Applicant is required, in reply to this action, to elect a single exemplary species to which the claims shall be restricted if no generic claim is finally held to be allowable. For example, applicant may elect polyvinyl alcohol for component B, and color pigment for component C. Election of polymer for component B is not sufficient, since it is not an exemplary species. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The claims are deemed to correspond to the species listed above in the following manner:

1. Claims 2-19

2. Claim 20

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: For both component B and C, the species claimed are not art recognized equivalents.

6. During a telephone conversation with Jason Voight on February 13, 2006 a provisional election was made with traverse to prosecute the invention of Group I, claims 1, 2, 5, 7, 10, 11, 20, 27 and 28, wherein the following species were elected: polyvinyl alcohols, polyvinylpyrrolidones and vinylpyrrolidone copolymers for component B, and color pigments or dye for component C. Affirmation of this election must be made by applicant in replying to this Office action. Claims 3, 4,

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6, 8, 9, 12-19, and 21-26 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 2, 5, 20, 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Gotsche (WO/00/18375) (Page: Lines: 1:5-12, 4:3-11, 19:10-34, Example 7).

10. In reference to claim 1, Gotsche discloses a coating agent, binder or film-forming excipient composition for solid substrates. Wherein the composition is comprised of:

a. Component A: A graft copolymer of polyvinyl alcohol and polyether, which is formed via polymerization of one vinyl ester of aliphatic C₁-C₂₄ carboxylic acids in the presence of a polyether.

b. Component B: An additional polymer, such as polyvinylpyrrolidone, polyvinylpyrrolidone copolymers, water-soluble cellulose derivatives such as hydroxypropylcellulose, hydroxypropylmethylcellulose, methylcellulose,

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hydroxyethylcellulose, acrylate and methacrylate copolymers, polyvinyl alcohols, polyethylene glycols, polyethylene oxide/polypropylene oxide block copolymers.

c. Component C: A conventional excipient such as colored pigments.

11. Gotsche discloses that the graft copolymer can be combined with additional polymers, wherein the ratio of the graft copolymer to the additional polymer is 1:9 to 9:1. Gotsche discloses that the graft copolymer can be applied in pure form or else together with conventional excipients to the substrate, wherein the weight percentage of the conventional excipients in the composition is exemplified as 3 wt %. Although Gotsche does not expressly disclose a composition comprised of components A, B, and C, he exemplifies a composition comprised of components A and C, and envisages the addition of component B thereof.

12. In reference to claims 2 and 5, component B is a polymer, specifically the elected species of polyvinyl alcohols, polyvinylpyrrolidones and polyvinylpyrrolidone copolymers.

13. In reference to claim 20, component C is the elected species of color pigment or dye.

14. In reference to claim 27-28, Gotsche discloses that solid substrates can be coated with the coating agent disclosed above. Additionally, the substrate can be a pharmaceutical formulation, such as tablets.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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16. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gotsche as applied to claim 1 above, and further in view of Cohen (US 4,256,864).

18. Gotsche fails to disclose that component B is a polyvinyl alcohol having a degree of hydrolysis of between 80 and 90 mol%. Hence attention is directed towards the Cohen reference, which discloses that commercial water-soluble PVA's (polyvinyl alcohols) are hydrolyzed poly vinyl acetates of about 88% (Column: Lines:: 3:4-19). Gotsche and Cohen are analogous art because they are from a similar problem solving area, formation of coating compositions. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to replace Component B of Gotsche with the hydrolyzed PVA of Cohen. It would have been obvious to use the commercially available hydrolyzed PVA with the expectation to form a film coating composition which dissolves as a function of pH.

19. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gotsche as applied to claim 1 above, and further in view of Hendrickson (US 3,566,969).

20. Gotsche fails to disclose that component B is a specific polyvinylpyrrolidone, as disclosed in claim 10. Hence attention is directed towards the Hendrickson reference, which discloses that N-vinylpyrrolidone homopolymers have a variety of uses, including functioning as an adhesive and hardening agent in medicinal tablets (Column: Lines:: 2:15-33). Gotsche and Hendrickson are

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analogous art because they are from a similar problem solving area, formation of coating compositions. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to replace Component B of Gotsche with the N-vinylpyrrolidone homopolymers of Hendrickson. The suggestion/motivation would have been obvious in order to improve the adhesion and hardening of the pharmaceutical presentations of Gotsche.

21. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gotsche as applied to claim 1 above, and further in view of Stambaugh (US 4,146,489).

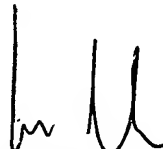
22. Gotsche fails to disclose that component B is a specific vinylpyrrolidone copolymer, as disclosed in claim 11. Hence attention is directed towards the Stambaugh reference, which discloses that N-vinylpyrrolidone alkyl methacrylate copolymers are commonly used as dispersant viscosity index improvers (Column: Lines:: 1:51-62). Gotsche and Stambaugh are analogous art because they are from a similar problem solving area, formation of graft copolymer with additives. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to replace Component B of Gotsche with the N-vinylpyrrolidone alkyl methacrylate copolymers of Stambaugh. The suggestion/motivation would have been obvious in order to improve the dispersancy and viscosity of the composition of Gotsche.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Saira Raza whose telephone number is (571) 272-3553. The examiner can normally be reached on Monday-Friday from 9am-5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (571) 272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



James J. Seidleck
Supervisory Patent Examiner
Technology Center 1700